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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/825,367
Filing Date: April 16, 2004
Appellant(s): SVEHLA ET AL.

Michael Verga
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/11/2009 appealing from the Office action mailed 10/29/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

3,738,366	BLOMBERG	6-1973
4,785,810	BACCALA et al.	11-1988
4,759,359	WILLIS et al.	7-1988
5,464,405	FUJITSU et al.	11-1995

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1,653,803	FISHER	12-1927
2,887,110	ROESCHMANN	5-1959
3,815,607	CHESTER	6-1974

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22, 25, 27, 35, 37, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Blomberg (U.S. 3,738,366). Blomberg discloses a forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (17) comprising contiguous first and second elongate regions having proximal and distal ends, the distal end of the first region being connected to the proximal end of the second region, a length of the second region having a concave cross-sectional shaped region (20; figure 6) wherein the proximal end of the concave-shaped cross-sectional region is configured to receive the electrode along a longitudinal axis through its geometric center since the proximal end can be considered to fall somewhere distal of grip portion (17) and has an open end and wherein the concave shape enables the second region to receive and support the electrode such that relative movement of the electrode is permitted while relative lateral movement of the electrode is substantially restricted, and a second flexible arm (18) comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region

(21), wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region, and wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode in a space defined by the concave region and the tip region.

Regarding claims 21 and 22, the concave region comprises a region having a substantially C-shaped cross-section. This can be considered a half-tube shaped section as well (see figure 6).

Regarding claim 25, the second regions of the arms are positioned at an angle of about 0 to 25 degrees from the first regions of the first and second arms.

Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the longitudinal axis of the second region of the first arm (figure 1).

Regarding claim 35, when the arms are compressed the distal ends of the second regions move toward each other.

Regarding claim 37, the forceps are capable of holding any of the electrode arrays listed in claim 37.

Claims 20-22, 25-27, 32, 37, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Baccala et al. (U.S. 4,785,810; "Baccala"). Baccala disclose a manually adjustable forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (region distal of pin (50)) comprising contiguous first and second elongate regions (second region starting at bend) having proximal and distal ends, the second region having a concave shaped region (16) near said distal end of the second region and a second

flexible arm (distal of pin (50)) comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region (28) wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode assembly in a space defined by the concave region and the tip region. The longitudinal axis of the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region and the concave region receives and supports an electrode assembly such that longitudinal movement of the electrode relative to the concave region is permitted and lateral movement of the electrode relative to the concave region is permitted.

Regarding claims 21 and 22, a cross section of the concave shaped region (26) will have a C-shaped cross section and substantially half-tube shaped.

Regarding claim 25, the second regions of the arms are at 30 degrees which is considered approximately 25 degrees (column 5 lines 8-13; obtuse angle of 150 degrees gives acute angle of 30 degrees).

Regarding claim 26, Baccala disclose an angle of 18 degrees because the obtuse angle can be between 90 and 180 degrees (162 degrees gives an acute angle of 18 degrees).

Regarding claim 27, a line through the center of the space defined by the concave cross-sectional shaped second region is substantially aligned with the longitudinal axis of the second region of the first arm.

Regarding claims 32, the tip region extends the length of the second region (entire portion after bend in arm) and has an approximately constant cross-section.

Claims 20-22, 27, 28, 32, 33, 35, 37, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Willis et al. (US 4,759,359; "Willis"). Willis disclose a forceps tool capable of

controlling an implantable electrode assembly comprising a first flexible arm comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (13), wherein the proximal end of the concave-shaped region is configured to receive the electrode along the a longitudinal axis of through the geometric center of the concave-shaped region and wherein the concave cross-sectional shape enables the second region to receive and support the electrode assembly such that relative longitudinal movement of the electrode is permitted while relative lateral movement of the electrode is substantially restricted and a second flexible arm comprising first and second contiguous elongate regions wherein the distal end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region (28) wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (see figure 3) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm (where 24 and 25 meet) and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the tip is in proximity to the concave cross-sectional shaped region, the electrode assembly is retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode.

Regarding claims 21 and 22, the region has a substantially c-shaped cross-section.

Regarding claim 27, a line through the center of the space defined by the concave cross-sectional shaped second region is substantially aligned with the longitudinal axis of the second region of the first arm.

Regarding claim 28, the concave cross-sectional shape has an aperture (15) positioned at its trough (14).

Regarding claim 32, the tip region extends the length of the second region of the second arm and comprises an approximately constant cross-section.

Regarding claim 33, the cross section of the tip region (28) is being considered substantially rectangular.

Regarding claim 35, the distal ends of the second regions move towards each other when the arms are compressed and move away from each other when the compression is released.

Regarding claim 37, the electrode array is not positively claimed and the device is capable of being used with any of the following: a cochlea, spinal, or auditory midbrain stimulation electrode array.

Claims 20-22, 27, 29, 30, 32, 34, 37, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujitsu et al. (US 5,464,405; "Fujitsu"). Fujitsu disclose a manually adjustable forceps tool for controlling an implantable electrode assembly comprising a first flexible arm comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (9), wherein the proximal end of the concave-shaped region is configured to receive the electrode along the a longitudinal axis of through the geometric center of the concave-shaped region and wherein the concave cross-sectional shape enables the second region to receive and support the electrode assembly (inside tube 10) such that relative longitudinal movement of the electrode assembly is permitted while relative lateral movement of the electrode assembly is substantially restricted and a second flexible arm comprising first and second contiguous elongate regions wherein the distal

end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (see figures 1 through 3) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the tip is in proximity to the concave cross-sectional shaped region, the electrode assembly is retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode assembly.

Regarding claims 21 and 22, see figure 3.

Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the second region of the first arm.

Regarding claims 29, 30, 32, and 34, the tip region of 3 has an approximately half-circular cross-section with a flat surface proximate to the concave region (9). The tip region has an approximately constant cross-section. The width of the flat surface is greater than the width of the space defined by the concave region.

Claims 20, 25, 27, 29, 31, 37, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Fisher (US 1,653,803). Fisher discloses a forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (12) comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (between wings 14, 15), wherein the proximal end of the concave-shaped region is configured to receive the electrode along the a longitudinal axis of through the

geometric center of the concave-shaped region and wherein the concave cross-sectional shape enables the second region to receive and support the electrode such that longitudinal movement of the electrode relative to the forceps is permitted while lateral movement of the electrode relative to the forceps is substantially restricted and a second flexible arm (11) comprising first and second contiguous elongate regions wherein the distal end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (figs. 2, 3) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm (at 8) and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the tip is in proximity to the concave cross-sectional shaped region, the electrode assembly is retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode.

Regarding claim 25, the second regions of the first and second arms are positioned at an angle of approximately 0 degrees from the first regions of the arms (first region being proximal half of arms distal of pivot point 8).

Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the second region of the first arm.

Regarding claim 29, the tip region (11) comprises a region having an approximately half-circular shaped cross-section wherein the half-circular shape is proximate to the concave cross-sectional shaped region when the tip is in proximity to the concave cross-sectional shaped region (see fig. 3; flat surface of 11 rests against handle "H").

Regarding claim 31, a width of the tip region has a width less than the width of the space defined by the concave cross-sectional shaped region (see fig. 3).

Claims 20, 27, 29, 30, 32, 34, 37, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Roeschmann (US 2,887,110). Roeschmann discloses a forceps tool capable of controlling an implantable electrode assembly comprising a first flexible arm (12) comprising contiguous first and second elongate regions, wherein the distal end of the first region is connected to the proximal end of the second region, a length of the second region comprising a concave cross-sectional shaped region (23), wherein the concave cross-sectional shape enables the second region to receive and support the electrode such that longitudinal movement of the electrode relative to the forceps is permitted while lateral movement of the electrode relative to the forceps is substantially restricted and a second flexible arm (13) comprising first and second contiguous elongate regions wherein the distal end of the first region is connected to the proximal end of the second region, the second region of the second arm having a tip region wherein a longitudinal axis through the concave-shaped cross-sectional region is substantially parallel to a longitudinal axis of the tip region (figs.1, 4) and wherein the proximal end of the first region of the first arm is connected to the proximal end of the first region of the second arm (at 17) and wherein application of a force to at least one of the first regions causes the tip region to travel toward the concave cross-sectional shaped region and when the tip is in proximity to the concave cross-sectional shaped region, the electrode is retained in a space defined by the concave cross-sectional shaped region and the tip region, thereby providing operator control of the longitudinal movement of the electrode.

Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the second region of the first arm.

Regarding claim 29, the tip region is being considered approximately half-circular shaped in cross-section, wherein a flat surface of the half-circular shape is proximate to the concave cross-sectional shaped region when the tip region is in proximity to the concave cross-sectional shape.

Regarding claim 30, the flat surface of the tip region has a width greater than the width of the space defined by the concave region.

Regarding claims 32 and 34, the tip region extends the length of the second region, comprises an approximately constant cross-section, and is approximately half-circular shaped in cross-section, wherein a flat surface of the tip region is proximate to the concave region.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willis. Willis disclose the invention substantially as stated above including that the second regions of the first and second arms are each positioned at a small angle relative to their first regions (see fig. 3). Willis is silent on the degree of the angle.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change this angle to 18 degrees since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)). That is, the instrument of Willis is used to grasp and insert lens material and an appropriately small bend angle allows better visualization of the end of the instrument without compromising access to smaller spaces.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Willis to choose a bend angle of 18 degrees since it would involve only routine skill in the art to find an optimum value.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willis in view of Chester (US 3,815,607). Willis discloses the invention substantially as stated above including a post (26) positioned on one of the arms proximate to the other arm when the tip region is in proximity to the concave region. Willis does not expressly disclose that the post member prevents the tip region from contacting the concave region.

Chester teaches that posts are used to ensure that the tip regions of forceps tools remain aligned and also to prevent the application of excessive force to the device (column 2 lines 55-60). It would have been obvious to one skilled in the art to modify Willis to ensure that the post prevents excessive force from being delivered to the tip region of the forceps tool in order to ensure that whatever is being held between the concave region and tip region is not damaged in any way. For example, when the device of Willis is used to fold a lens prosthesis, it would have been obvious to one skilled in the art in view of Chester to provide the post in a manner that results in the concave region and tip region having enough clearance in the closed configuration to fit a prosthesis within the space without applying excessive force to the prosthesis.

(10) Response to Argument

Appellant argues that the references of Blomberg, Baccala, Willis, Fujitsu, Fisher, and Roeschmann each fails to disclose forceps tools that meet the limitation "wherein the proximal end of said concave-shaped cross-sectional region is configured to receive said electrode assembly along a longitudinal axis through the geometric center of said concave-shaped cross-sectional region." It is noted that most of the language within this limitation is functional

language. The only structure required by this limitation is that the proximal end of the concave-shaped region has a structure capable of receiving an electrode assembly along the claimed longitudinal axis. The electrode assembly is not being claimed and therefore any electrode assembly of any size and shape that is capable of implantation into the body can be used with the claimed forceps tool. In the following arguments, the distal end of the forceps tools are being considered the tip end of the forceps where the arms are separate and the proximal end is being considered the end where the forceps arms are connected to one another, which is in agreement with the claims.

In the case of Blomberg, Appellant argues that, because opposing members 2 and 3 of Blomberg are affixed to one another and extend away from the end within a single plane, the device of Blomberg is not capable of meeting the limitation "wherein the proximal end of said concave-shaped cross-sectional region is configured to receive said electrode assembly along a longitudinal axis through the geometric center of said concave-shaped cross-sectional region." However, this feature of Blomberg does not prevent an electrode from being received in the claimed manner. For example, if the concave-shaped cross-sectional region of the second region is considered the region of arm (2) extending from tip (20) to about the halfway point between the tip (20) and finger grips (17) as shown in figure 1, a user could insert a small electrode into the tip region (20) and push it along the longitudinal axis of the concave-shaped region until it is received in the proximal end of this region. Alternatively, if the forceps arms are opened, an electrode may be inserted in a direction orthogonal to the longitudinal axis so that the electrode is received in the proximal end of the concave region along the axis. In other words, the claim does not necessitate that the electrode is inserted along the claimed axis. Rather, it must be received along the axis.

In the case of Baccala, Appellant argues that the longitudinal axis of the concave region is physically obstructed past its proximal end and therefore the device cannot meet the claim limitation discussed above. However, an electrode can be received into the proximal end of the concave section along the longitudinal axis of the concave portion by inserting the electrode into the distal end of the concave portion and pushing it proximally (toward the handles) along the longitudinal axis of the concave region until the electrode is received in the proximal end of the concave region similar to the manner discussed above regarding Blomberg. In other words, the obstruction does not block the electrode from being advanced from the distal end in a proximal direction to the proximal end of the concave region.

In the cases of Willis and Fisher, Appellant similarly argues that the longitudinal axis of the concave region of each of these devices extends through intermediate sections of the forceps and the proximal end of the concave region is physically obstructed along this axis. However, an electrode may be inserted into the open distal end of the concave region of either Willis or Fisher and advanced proximally along the longitudinal axis of the concave region until it is received within the proximal end of the concave region. There is no obstruction at the distal end of the concave region which prevents an electrode from entering the concave region at the distal end and then advancing to the proximal end of the concave region along the claimed axis. Additionally, the concave regions of both Willis and Fisher are open at both their proximal and distal ends. Although the longitudinal axis is obstructed proximal of the proximal end region of the concave region by intermediate portions (17 in Willis, 8 in Fisher), an electrode may enter the proximal end region from either direction as long as it is inserted distal of this obstruction and then advanced in the appropriate direction into the proximal end region.

Roeschmann is capable of meeting this limitation since an electrode can be inserted into the open distal end of the concave portion (portion 23 shown in figures 1 and 4) and advanced

proximally along the longitudinal axis through the geometric center of the concave portion until it is received in the proximal end of this region (23).

Fujitsu is capable of meeting this limitation since an electrode can be inserted into the open distal end of tube (10) which lies within concave region (9) and advanced proximally along the longitudinal axis through the geometric center of the concave portion until it is received in the proximal end of this region. Appellant also argues that Fujitsu does not meet the limitation of a tip region being configured to retain an electrode assembly, thereby providing operator control of the relative longitudinal movement of the electrode assembly. However, the tip region of Fujitsu is being considered to extend proximally from the distal-most point to include a portion of the forceps that includes the tube (10). This tip region provides the operator with control of the relative movement of the electrode assembly. For example, the user may control this relative movement by changing the orientation of the forceps so that an electrode held within the tube (10) in the tip region moves from a higher end to the lower end of the tip region as a result of gravity and the orientation of the forceps. This can be considered providing operator control because the user is determining the orientation of the tip, which determines where within the tip the electrode will rest.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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